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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/069,307	INGENITO, EDWARD	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/04/08 & 12/04/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-34,55-58,63,69,70 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-34, 55-58, 63, 69-70, 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 11/04/08 and 12/04/08 has been entered.

Claims 1, 3-34, 55-58, 60-63, 65-73 are present for examination.

Claims 2, 35-54, 59, 64 are cancelled.

Specification

Applicant states that Applicant resubmits a copy of Specification as originally filed. However, the copy of the Specification still not shows nor filed in the record. Please check with the filling paper department.

The Specification of this application is missing. Examiner requests that Applicant re-sends another Specification.

For examining purpose, the Examiner gets the information from the relate application number 10/649232 (US 2004/0038868).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 3, 9, 13-16, 18-19, 24, 31-34, 55-58, 60-63, 65-67, 69-72 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Perkins et al. (US 6,287,290).

Perkins discloses a methods and systems and kits for lung volume reduction that comprising: advancing a bronchoscope/catheter in to a region of a lung targeted (DR, see Fig. 4-6) for reduction in a patient (col. 2, lines 15-20, col. 8, lines 18+);

introducing material (gases/liquids/fibrin) through the bronchoscope into a diseased alveolar region within the targeted region (col. 2, lines 29-43, col. 3, line 24-32, col. 10, lines 37+);

Perkins further discloses that the method of his invention can be comprises introducing material such as sealing/adhesive material with fibrin glue, or introducing plug 282 with hydrated collagen hydrogel material (col. 10, lines 37-41). As noted that, the sealing fibrin/glue not only causes collapse the diseased alveolar region but also adhering the collapsed diseased alveolar region also.

Perkin clearly states that: sealing or occluding the air passage leading to the collapsed tissue region/reduce the volume of the targeted region (including alveolar region) within the patient's lung; the sealing can be performed in variety of ways, including adhesion, gluing, and the like (col. 10, lines 37-41). In other words, introducing plug is one of the methods of occluding the air passage.

wherein the material (fibrin glue if the sealing method is applied) introduced through the bronchoscope induces collapse of the targeted region (col. 2, lines 30-35, col. 3, lines 22-58); promotes adhesion between one collapsed portion of the lung and another (see Figs. 4-11); and promotes fibrosis /fibrin glue in or around the collapsed region of the lung (col. 2, lines 37-43, col. 4, lines 10-20).

It is noted that although Perkin teaches optionally sealing with fibrin glue or occluding an air passage leading or occluding an air passage leading to the collapsed region of the lung by delivering a plug contained adhesive or sealing material (hydrated collagen, hydrogel). Therefore, one skill in the art would apply the method teachings of Perkin for reducing lung volume.

Regarding claims 13, 19, suitable plugs include swellable collagen matrices which hydrate and expand within the air passage so that they fully occlude/block the passage (col. 2, lines 34-38).

Regarding claims 14-15, 24, Perkins discloses a method comprising: collapse the diseased alveolar region by aspiration air, and any other gases or liquids that maybe introduced; introducing sealing fibrin/glue material adhere one portion of collapsed region to another. As noted that, the sealing fibrin/glue not only causes collapse the diseased alveolar region but also adhering the collapsed diseased alveolar region also;

and promoting fibrosis (fibrin glues) in or around the collapsed region of the lung; the method is performing using a bronchoscope/catheter.

Regarding claims 16 and 18, Perkins discloses that sealing or occluding the air passage leading to the collapsed tissue region of the lung is achieved by administering a substance (fibrin) that increases the surface tension of fluids lining the alveoli in the targeted region (col. 10, line 37+).

Regarding claims 55-58, 60-63, 65-67, 69, 72-73, Perkins discloses the method comprising: introducing a material (seal/ adhesive/fibrin glues or cyanoacrylate into the lung and collapsing the diseased region to reduce the volume of the lung (col. 10, line 35+); blocking air passage by inducing the plugs include swellable collagen (col. 2, lines 34-38), or balloon catheter (Figs. 4-6, 8).

Regarding claim 70, absorbable gas (oxygen rich gas) can be introduced prior to collapsing the region (col. 6, lines 59+, col. 9, line 45+

Claims 6-8, 10-12, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al in view of Clark et al. (US 6,723,302).

Perkins meets the claim limitations as described above but fails to disclose the fibrin/fibrinogen comprises component of materials listed in claims 6-7. It is noted that during the reducing lung volume treatment, the lung region will be damaged or wounded; therefore, using sealing/adhesive/fibrin is very well-known in the art.

Clark discloses that the fibrin or fibroblasts growth factor comprises a component of the extracellular matrix (ECM) or an ECM-like substance; the component of the ECM comprises a fibronectin (Fn), hyaluronic acid (HA), see col. 4, lines 9+); peptide (col. 14, lines 50-62, col. 18, lines 37-47).

At the time of the invention, it would have been obvious to use a component of the ECM of Clark in order to wound repair. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material listed in claims 6-8, 10-12 and 28, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claims 4-5, 17, 20-21, 25-27, 29-30, 68, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson et al. (US 5,739,288).

Perkins meets the claim limitations as described above but fails to disclose the fibrin comprises a polypeptide growth factor, the use of fibrinogen and a fibrinogen activator such as thrombin.

Edwardson discloses a fibrin further comprises a polypeptide growth factor, a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 1, line 40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery times.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson in further view of Antanavich et al. (US 5,814,022).

Perkins in view of Edwardson meets the claim limitations as described above but fails to include the composition comprising 3-12% fibrinogen.

Antanavich discloses a method and apparatus for applying tissue sealant that includes that use of an adhesive protein solution having a fibrinogen content of from 3 to 12% with clot promoting factor XIIIa and further notes that one reason for this arrangement is that the strength of the sealant is proportional to the fibrinogen concentration. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 10, line 40) and Antanavich teaches an enhanced fibrin sealant composition a combination is proper.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to incorporate the concentration of fibrinogen as taught by Antanavich et al. into the invention of Perkins in order to have an adhesive protein solution that is less prone to clogging before administered to the therapeutic site as taught by Antanavich et al. Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Response to Arguments

Applicant's arguments filed 11/04/08 have been fully considered but they are not persuasive.

1. Applicant argues that the method for lung volume reduction discloses in Perkins do not target the alveolar region of the lung.

Perkin clearly shows that the method for lung volume reduction target at the diseased region DR or CLT (such as alveolar region of the lung), see Figs. 4-11.

2. Applicant argues that in the claimed methods the material does not serve merely as a plug to occlude the air passage leading to the collapsed tissue region as in Perkins, but acts to induce collapse, promote adhesion, and promote fibrosis.

Although reference Perkin does not explicitly state exactly same the claim languages, however, the statements of method for reducing lung volume of claimed invention do not distinguish claims over prior art, which can lead in the same manner or same result. Please see rejection and explanations above for more details.

3. Applicant argues that Perkin does not teach or render "obvious to try" all of the limitations of Applicant's amended claims. The combination of Perkins and Edwardson, Antanavich do not render unpatentable any of the amended claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case, it is noted that during the reducing lung volume treatment, the lung region will be damaged or wounded; therefore, using sealing/adhesive/fibrin is very well-known in the art. Perkins does not clearly disclose that the material of fibrin comprises all materials listed in claims above. While, Edwardson, Antanavich or Clark (new cited reference) suggests the benefits of materials listed in claims above for enhancing the repair of the tissue damage or wound. Therefore, one skill in the art would provide other materials listed in claimed invention, for enhancing the repair of the tissue damage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763